REMARKS

Claims 3, 4, 14, 15, 21, 29, 30, 34, 40, 51-64 and 66-76 are pending. Claims 1-2, 5-14, 16-20, 22-28, 31-33, 35-39, 41-50, and 65 are canceled.

35 U.S.C. § 103 Rejections

Applicants submit that the rejections under 35 U.S.C. § 103 addressed below are in error for the following reasons.

Legal Framework

Initially, the determination of whether a claim is obvious under 35 U.S.C. § 103 depends on at least four underlying factual issues set forth in *Graham v. John Deere Co. of Kansas City*[1]: (1) the scope and content of the prior art; (2) differences between the prior art and the claims at issue; (3) the level of ordinary skill in the pertinent art; and (4) evaluation of any relevant secondary considerations. In April 2007, the Supreme Court affirmed the *Graham* analysis as the framework for determining obviousness.[2]

In addressing the scope and content of the prior art, references are not pertinent to an obviousness inquiry if they are not from analogous art.[3] A reference is analogous art if: (1) the reference is from the same field of endeavor, regardless of the problem addressed, or (2) the reference is not within the inventor's field of endeavor, yet it is reasonably pertinent to the particular problem addressed by the inventor. In *Clay*, the PTO asserted that the claimed invention and the Sydansk reference were part of a common endeavor of "maximizing withdrawal of petroleum stored in petroleum reservoirs."[4] Sydansk taught the

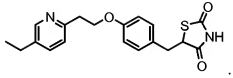
> use of a gel in unconfined and irregular volumes within generally underground natural oil-bearing formation to channel flow in a desired direction; Clay teaches the introduction of gel to the confined dead volume of a man-made storage tank.[5]

[1] 383 U.S. 1, 17, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966).
[2] *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1739 (2007).
[3] *In re Clay*, 23 U.S.P.Q.2d 1058, 1060 (Fed. Cir. 1992).
[4] *Id.*
[5] *Id.*

However, the Federal Circuit disagreed with the Office and held that Clay's field of endeavor was "*storage* of refined liquid hydrocarbons" and Sydansk's invention was directed to the "*extraction* of crude petroleum."

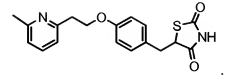
The second step of the *Graham* analysis requires consideration of the differences between the prior art and the claims at issue. It is well established law, that, where, as here, the claims at issue are directed toward a chemical compound, the analysis of the *Graham* factor on the differences between the claimed invention and the prior art often turns on the structural similarities and differences between the claimed compound and the prior art compounds.[6] Obviousness based on structural similarity thus requires identification of some motivation that would have led one of ordinary skill in the art to select and then modify a known compound (i.e. a lead compound) in a particular way to achieve the claimed compound.[7]

In *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*,[8] the Federal Circuit addressed the obviousness issue for structurally similar chemical compounds. In *Takeda*, the claim at issue recited pioglitazone (5-{4-[2-(5-ethyl-2-pyridyl)ethoxy] benzyl}-2,4-thiazolidinedione) having the following structure:



An ethyl substituent is attached to the 5-position on the pyridyl ring.

Alphapharm filed an ANDA to manufacture and sell a generic version of pioglitazone. According to Alphapharm, Takeda's claimed compound would have been obvious over the prior art compound TZD ("compound b": a pyridyl ring with a methyl (CH_3) group attached to the 6-position of the ring),[9] having the following structure:



[6] *See Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1377; 81 USPQ2d 1324 (Fed. Cir. 2006).
[7] *See Takeda Chem. Indus. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356; 83 USPQ2d 1169 (Fed. Cir. 2007).
[8] 492 F.3d 1350 (Fed. Cir. 2007).
[9] *Id.* at 1354.

Alphapharm argued that one of ordinary skill in the art would select compound b for antidiabetic research and then make "two obvious chemical changes: first, homologation, i.e., replacing the methyl group with an ethyl group, which would have resulted in a 6-ethyl compound; and second, 'ring-walking,' or moving the ethyl substituent to another position on the ring, the 5-position, thereby leading to the discovery of pioglitazone."[10]

The district court found, however, that one of ordinary skill in the art would not have selected compound b from the "hundreds of millions" of possible compounds. "[T]he prior art did not suggest to one of ordinary skill in the art that compound b would be the best candidate as the lead compound for antidiabetic research."[11] Moreover, when determining the obviousness of new chemical compounds, there must be "some reason that would have led a chemist to modify a known compound in a particular manner to establish *prima facie* obviousness."[12]

Once a reason to modify a known compound is found, the skilled person must also have a reasonable expectation that such a modification will be successful or beneficial in some way. In many chemical cases a "reasonable expectation of success" is not always found, as the Federal Circuit stated in *Eisai Co. v. Dr. Reddy's Laboratories, Inc.*[13] :

> First, KSR assumes a starting reference point or points in the art, prior to the time of invention, from which a skilled artisan might identify a problem and pursue potential solutions. Second, KSR presupposes that the record up to the time of invention would give some reasons, available within the knowledge of one of skill in the art, to make particular modifications to achieve the claimed compound. See Takeda Chem. Indus. v. Alphapharm Pty., Ltd., 492 F.3d 1350, 1356 (Fed. Cir. 2007). ("Thus, in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound."). Third, the Supreme Court's analysis in KSR presumes that the record before the time of invention would supply some reasons for narrowing the prior art universe to a "finite number of identified, predictable solutions," 127 S. Ct. at 1742. In Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc., 520 F.3d 1358, 1364 (Fed. Cir. 2008), this court further explained that this "easily traversed, small and finite number of alternatives . . . might support an inference of obviousness." To the extent an art is unpredictable, as the chemical arts often are, KSR's focus on these "identified, predictable solutions" may present a

[10] *Id.* at 1357.
[11] *Id.* at 1358.
[12] *Id.*
[13] *Eisai Co. v. Dr. Reddy's Laboratories, Inc.*, 87 U.S.P.Q.2d 1452 (Fed. Cir. 2008).

difficult hurdle because potential solutions are less likely to be genuinely predictable. (Emphasis added)

Notenbomer in view of Cohen

In the context of this legal precedent, reconsideration is respectfully requested of the rejection of claims 3, 4, 14, 15, 21, 29, 30, 34, and 51-59, 62-64, 66-73, and 76 as unpatentable over Notenbomer (EP 0 730 494) in view of Cohen et al. (U.S. Patent No. 6,558,665) under 35 U.S.C. § 103(a). Claim 3 is directed to an oral or rectal pharmaceutical composition comprising a pharmaceutically acceptable excipient and core-shell particles. These core-shell particles comprise a core component and a shell component; the core component comprises a potassium-binding cation exchange polymer and the shell component having a thickness ranging from about 0.002 microns to about 50 microns. The shell component is essentially not disintegrated during residence and passage through the gastrointestinal tract of an animal subject. Claim 53 is similar to claim 3 except it requires the weight ratio of the shell component polymer to the core component polymer range from about 0.0001:1 to about 0.5:1. Notenbomer generally discloses methods and particles for binding monovalent cations. The particles have a nucleus and a coating; the nucleus contains a cation exchange material and the coating comprises a membrane that is permeable for monovalent cations. This coating is disclosed as being more permeable for monovalent cations than for bi- or higher valent cations. Exemplified cation exchange materials are polyphosphate and polystyrene sulfonate resins. Exemplified coatings are cellulose acetate and crosslinked polyethyleneimine. Generally, these particles are disclosed for treating hypertension. Notenbomer does not disclose the thickness of the shells or the shell to core weight ratio as required by claims 3 and 53, respectively. Thus, Notenbomer does not describe all the elements of claims 3 or 53 because it does not describe a shell component the required thickness or the required shell to core weight ratio.

Cohen et al. describes methods of coating particles with a coating of uniform thickness that conforms to the size and shape of the particles. In particular, the particles coated are islet cells that are used to treat diabetes. The particles can be coated with poly(ethylene glycol) or

poly(oxyethylene)-poly(oxypropylene) block copolymers or agarose that have a thickness of from about 10 microns to about 20 microns.[14]

The Office states that it "would have been obvious to coat the particles to a uniform thickness of 10-20 microns as disclosed in the '665 patent" and a skilled person "would have been motivated to combine the teachings [disclosure] and suggestions of the prior art as such with an expected result of a stable coated cation exchange resin useful in removing cations from the intestinal tract of a human."[15] This reasoning can be compared to that in *Clay*, where the PTO asserted that the claimed invention and the Sydansk reference were of a common endeavor because they were directed to "maximizing withdrawal of petroleum stored in petroleum reservoirs."[16] But in this case, the PTO articulates no reason why the Cohen patent is analogous art to either the invention or Notenbomer. Applicants' endeavor is development of oral potassium binders that have increased selectivity by using a coating of the claimed thickness.[17] The Cohen patent is directed to methods of coating particles in order to develop coated islet cells for treating diabetes. The encapsulation of the cells by the coating provides "immunoisolation of the cell by providing a semi-permeable barrier between the host and the transplanted tissue."[18] While the Office states that the reason the Cohen patent and the Notenbomer patent can be combined is because of an "expected result of a stable coated cation exchange resin"[19], this reason does not place Applicants' invention in the same field as the Cohen patent nor does it address the problem disclosed in either Applicants' specification or the Notenbomer patent.

For example, there are many differences between binding sodium and potassium even though they are similar target ions. These differences include variances in the relative and absolute amounts of sodium and potassium along the gastrointestinal tract; the amounts of sodium and potassium depending upon the condition suffered by the patient; and the selectivity of a cation exchange polymer for sodium and potassium ions.

The amount of sodium as compared to the amount of potassium available for binding will be different because the relative and absolute amounts of sodium and potassium in the

[14] See Examples 1-3.
[15] See Office action dated March 9, 2009 at page 9.
[16] *Id.*
[17] See specification at paragraph [0019] and original claim 43.
[18] See U.S. Patent No. 6,558,665 at column 8, lines 26-28.
[19] See Office action dated March 9, 2009 at page 9.

gastrointestinal tract change depending on location (e.g., distance from the stomach). For example, Fordtran et al.,[20] who studied the sodium and potassium concentrations in the upper GI after different meals, (see especially Figs 2, 4 and 10), found that at the end of the ileum, the sodium concentration is relatively high, whereas the potassium concentration is relatively low. However, at the end of the gastrointestinal tract, the contents have a relatively high potassium concentration and a relatively low sodium concentration.[21]

Further, when a subject suffers from hyperkalemia, the body compensates for the high intracellular potassium concentration in various ways, and thus, the amount of sodium or potassium found within the gastrointestinal tract in a hyperkalemic patient can be much different from the sodium and potassium concentrations of healthy people or patients suffering from various diseases. For example, clinical evidence shows that hyperkalemic patients with renal dysfunction or chronic kidney disease (CKD) who are not on dialysis increase potassium excretion in the terminal colon, as described in the review by Musso.[22] Specifically, Musso states:

> During CKD, the small intestine makes a greater contribution to potassium excretion than it does under normal conditions. Intestinal potassium excretion rises during chronic renal failure and the body can eliminate an additional 10–20 mmol of potassium by this route. Colonic potassium secretion begins to adapt when glomerular filtration is reduced to around one-third of normal and when renal failure is advanced, this route may account for as much as 30–70% of total potassium excretion.

This means that depending on the patient, the same cation-binding polymer can have a different effect on potassium and sodium concentrations in the body. Patients on drugs that affect potassium secretion, such as potassium sparing and non-potassium sparing diuretics, will have various perturbations in their sodium/potassium balance that may affect potassium and sodium availability in the gastrointestinal tract. Thus, these patients could also experience a

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[20] J.S. Fordtran et al. "Ionic Constituents and Osmolality of Gastric and Small-Intestinal Fluids after Eating," *Am. J. Digestive Dis*. **1966**, *11(7)*, 503.

[21] O. Wrong et al., "*In Vivo* Dialysis of Faeces as a Method of Stool Analysis," *Clin. Sci*. **1965**, *28*, 357-375. (see Figures 2 and 4).

[22] C.G. Musso, "Potassium Metabolism in Patients with Chronic Kidney Disease (CKD), Part I: Patients Not on Dialysis (Stages 3-4)," *International Urology and Nephrology* **2004**, *36*, 465-468.

different effect on potassium and sodium concentrations in the body upon administration of a cation-binding polymer.

Just like Alphapharm in *Takeda*, the PTO is arguing that it would have been obvious to one of ordinary skill in the art to choose the specific polymeric coatings of Cohen from the millions of possible available coatings in the prior art because the coating methods were similar. As *KSR v. Teleflex* and *Takeda v. Alphapharm* emphasize, it is important to "identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does."[23] Although the Office states that the similar coating methods and the expected result of a stable coated cation exchange resin would be the reason for combining the references, similar to *Ex parte Meagher*, such a general statement for the reason for combining the references does not address the specific claim elements, e.g., why one would select the Cohen patent from the multitude of references describing the same coating method.[24]

Even if the PTO is relying on the Cohen reference as non-analogous art recited to show the common knowledge of one of ordinary skill in the art, no reason is provided as to why a skilled person would have had reason to select the narrow range of shell thickness in the Cohen patent to modify the core-shell particles of the Notenbomer patent. Also, the Cohen patent cannot properly be combined with the Notenbomer patent because a skilled person would not have considered the teachings of Cohen (directed to encapsulating cells to prevent transplant rejection) when developing core-shell particles that have a shell thickness that increases the amount of potassium bound by the particles. For example, core-shell particles can advantageously have a shell that is thick enough to meaningfully reduce the permeability of the shell polymer for divalent cations. Also, core-shell particles can have shells thin enough to maintain an acceptably high permeability rate for monovalent cations. Cohen describes a coating that is not used to increase the amount of potassium bound by a polymeric core and Cohen provides no reason that the skilled person would use such a coating to modify the particles of Notenbomer. Thus, the two patents are not in the same field of endeavor and do not address the

[23] *KSR v. Teleflex, Inc.*, 82 U.S.P.Q.2d 1385, 1396.

[24] *Ex parte Meagher*, Appeal no. 2008-3613; Application No. 10/380,898 decided September 22, 2008 at page 15 (describing that combining references for the purpose of "obtaining a conversion coating having good corrosion resistance and good top coat adhesion properties-which are likely goals of virtually every conversion coating composition-do not provide the ordinary coating formulations chemist with a reason to systematically vary" the prior art compositions to arrive at the claimed composition.).

same problem, so they are not analogous art. Also, Cohen does not evidence common general knowledge of a person of ordinary skill in the art that would have provided a reason to combine the two patents.

In sum, the PTO has failed to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed invention does. There is simply no reason that a skilled person would have combined the Notenbomer and Cohen patents to arrive at the claimed invention.

Applicants submit that the PTO is engaging in the exact hindsight bias that the Court has repeatedly urged must be avoided. The PTO has not provided a reason why a skilled person would choose the coating thicknesses as described in the Cohen patent. Hence, the only way that the PTO could arrive at this conclusion is based on the teachings of the instant application while disregarding what the art would have actually led a skilled person to do.

Claim 53 is similar to claim 3 and is patentable over Notenbomer in view of Cohen for at least the same reasons described above. In sum, claims 3, 4, 15, 21, 29, 30, 34, and 51-64, and 66-76 are patentable over Notenbomer (EP 0 730 494) in view of Cohen et al. (U.S. Patent No. 6,558,665) under 35 U.S.C. § 103(a).

Notenbomer in view of Cohen and Chong

Reconsideration is respectfully requested of the rejection of claims 3, 34, 40, and 53 as unpatentable over Notenbomer (EP 0 730 494) in view of Cohen et al. (U.S. Patent No. 6,558,665) and Chong et al. (U.S. Patent No. 4,389,590) under 35 U.S.C. § 103(a). Claims 3 and 53 are described above. Claim 34 is directed to a method of treating an animal subject suffering from a disease selected from the group consisting of renal insufficiency, renal failure, end stage renal disease (ESRD) and combinations thereof, comprising administering to the subject in need thereof an effective amount of the pharmaceutical composition of claim 3 or 53. Claim 40 is directed to a method of treating an animal subject suffering from hyperkalemia comprising administering the subject in need thereof an effective amount of the pharmaceutical composition of claim 3 or 53.

Notenbomer and Cohen are described above. Chong et al. (the '590 patent) describe liquid cation exchange materials comprising emulsions of submicroscopic, spherical beads

having diameters from about 0.01 to about 1.5 microns and having from about 0.7 to about 1.5 cation exchange functional groups per monomer unit wherein the cation exchange functional groups are strong acid groups or free acid forms of weak acid groups. The reference further describes that strongly acidic resins in the sodium form can be used for treating hyperkalemia. The Office asserts that from the "suggestion of the '590 patent to use acid cation ion exchange resins to treat hyperkalemia, the artisan of ordinary skill would have been motivated to apply the composition of the '494/'665 patent combination in order to remove excess potassium ions from the body effectively treating hyperkalemia in a human patient in need of treatment."[25]

As described above, claim 3 and 53 require the shell component of the core-shell particle to be a crosslinked polymer having either a specific shell thickness or a specific shell:core ratio. Cohen describes various coating for islet cells for treating diabetes. Further, Chong et al. do not describe any shell materials, is directed to preparing an exceptionally small particle size, spherical ion exchange resins, and is only cited for the disclosure that strongly acidic resins in the sodium form can be used for treating hyperkalemia. In fact, the particle size of Chong et al. is so small (less than 1.5 microns) that such small particles would be absorbed by the body, and thus not function to bind potassium in the gastrointestinal tract (See Payne at al., Nature, 1960 – article attached, suggesting that particles in the 1-5 micron range can pass through the small intestine wall and move throughout the body). Thus, Chong is not properly combined with Notenbomer because Chong is not directed to the problem of claims 3, 34, 40, 53 or of Notenbomer.

Further, the combination of the Notenbomer and Chong teachings do not provide a teaching of the shell thickness required by claim 3 or the shell:core thickness required by claim 53. If it is asserted that these limitations are inherently met by Notenbomer, such an assertion is improper. The *Spormann* court stated that obviousness and inherency are different questions and "[t]hat which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown."[26] Thus, since it is unknown whether the Notenbomer particles would have the claimed elements, the claimed pharmaceutical compositions cannot be obvious from the Notenbomer disclosure.

[25] See page 10 of Office action dated March 9, 2009.
[26] *In re Spormann*, 150 U.S.P.Q. 449, 452 (C.C.P.A. 1966).

Moreover, for claim 34, the Office ignores the requirement that the subject is suffering from renal insufficiency, renal failure, end stage renal disease (ESRD), or a combination thereof. Therefore, the elements of claim 34 are not disclosed in the cited references.

In sum, claims 3, 34, 40, and 53 are patentable in view of the cited references.

Notenbomer in view of Cohen et al., Shimizu et al. and Macek et al.

Reconsideration is respectfully requested of the rejection of claims 3, 53, 60, 61, 74, and 75 as unpatentable over Notenbomer (EP 0 730 494) in view of Cohen et al. (U.S. Patent No. 6,558,665), Shimizu et al. (U.S. Patent No. 5,824,339) and Macek et al. (U.S. Patent No. 3,499,960) under 35 U.S.C. § 103(a). Claims 3 and 53 are described in detail above, claims 60, 61, 74, and 75 further require a vinylic or an acrylic or methacrylic monomer. The Office asserts that it would have been obvious "to combine the teachings and suggestions in order to arrive at a palatable oral formulation useful in the treatment of a variety of ion related disorders."[27]

Notenbomer and Cohen are described above. Shimizu et al. disclose drug delivery systems of effervescent compositions of core-shell powders having a fine granular core spray-coated with a liquid mixture containing a water-soluble polymer, a physiologically active substance, and an enteric coating. Further, Shimizu et al. disclose water-soluble polymers of hydroxypropylcelluose (HPC), polyvinylpyrrolidone, hydroxypropylmethylcellulose (HPMC), methylcellulose, carboxymethylcellulose sodium, sodium polyacrylate, polyvinylalcohol, sodium alginate, guar gum, etc.[28] For use as an enteric coating, Shimizu discloses cellulose acetate phthalate (CAP), hydroxypropylmethylcellulose phthalate (HP-55), hydroxymethylcellulose acetate succinate, acrylic copolymers (e.g. Eudragit L30D-55), carboxymethylethylcellulose, and shellac.[29]

Macek et al. disclose polymers used to remove bile acids; the polymers disclosed are polystyrene resins crosslinked with divinyl benzene and functionalized through chloromethylation of the aromatic rings and replacement of the chlorine atom with a tertiary amine such as trimethyl amine to form a trimethyl ammonium group attached to the aromatic

[27] See page 11-12 of Office action dated March 9, 2009.
[28] See U.S. Patent No. 5,824,339 at column 4, lines 40-46.
[29] See U.S. Patent No. 5,824,339 at column 7, lines 17-21.

rings. Thus, the polymers are amine polymers that can be coated with carboxypolymethylene crosslinked with polyallyl sucrose or an acrylic acid polymer crosslinked with polyallylsucrose.

Similar to Alphapharm in *Takeda*, the PTO is arguing that it would have been obvious to one of ordinary skill in the art to choose the specific polymeric coatings in Shimizu and Macek from millions of possible available coatings "in order to provide sufficient permeability of potassium ions into the cation exchange core"[30] of the Notenbomer particles. As *KSR v. Teleflex* and *Takeda v. Alphapharm* emphasize, it is important to "identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does."[31] As described above, the teachings of Cohen are not properly combined to provide core-shell particles having a thickness that is thick enough to decrease the permeability of divalent cations yet thin enough to exchange monovalent cations in a time frame for the core-shell particles to bind potassium low in the colon. The teachings of Shimizu and Macek do not remedy this deficiency. Shimizu is directed to effervescent compositions that do not contain nondisintegrating shell components. Macek is directed to anion exchange cores with negatively charged shells that bind bile acids (negatively charged ions), and would not bind potassium (a positively charged ion). Further, since the most common bile acids have molecular weights of at least 375 g/mol, the permeability of a coating for particles to bind bile acids (e.g., charge and pore size) would have been much different than the charge and pore size needed to provide the required potassium permeability to the shell component of the claimed core-shell particles. Thus, neither Shimizu nor Macek would have provided a reason for a skilled person to modify the particles of Notenbomer to arrive at the claimed core-shell compositions.

Further, although the Office states that the palatable oral formulations would be the reason for combining the references, similar to *Ex parte Meagher*, such a general statement for the reason for combining the references is likely the goal of every reference concerned with coated pharmaceutical particles for oral administration. Further, there is no reason provided in the cited art or reliance on knowledge in the art that would have led a skilled person to select the coatings of Shimizu or Macek to modify the core-shell particles of the Notenbomer patent. For example, Shimizu and Macek are directed to different problems than Notenbomer or the claimed

[30] See page 11 of Office action dated March 9, 2009.
[31] *KSR v. Teleflex, Inc.*, 82 U.S.P.Q.2d 1385, 1396.

invention. Notenbomer and the claimed invention are directed to core-shell particles for binding potassium. In contrast, Shimizu is directed to effervescent compositions that provide delayed release of the active agent and disclose shell polymers that are water soluble. Shimizu further describes acrylic acid polymers as enteric coatings that are intended to disintegrate or dissolve at a particular position in the gastrointestinal tract.

Thus, since the problem of Shimizu is different from Notenbomer's, not only is it not properly combined with Notenbomer, but it does not provide a reasonable expectation that the modified particles would have the claimed elements including shell nondisintegration. Further, Macek is directed to bile acid binders that have a core of an amine polymer and a shell that can be an acrylic acid polymer and provides a palatable composition. An amine polymer core binds anions (e.g., bile acids) and would not be a potassium binding cation exchange polymer as required by the instant claims.

Therefore, the PTO has failed to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed invention does. There is simply no reason that a skilled person would have combined Notenbomer and the Shimizu and Macek patents to arrive at the claimed invention. Applicants submit that the PTO is engaging in the very hindsight bias that the Court has repeatedly urged must be avoided. The PTO has not provided a reason why a skilled person would have chosen the coatings of Shimizu or Macek from the universe of possible coatings. Hence, the only way that the PTO could arrive at this conclusion is based on the teachings of the instant application while disregarding what the art would have actually led a skilled person to do. Thus, claims 3, 53, 60, 61, 74, and 75 are patentable over Notenbomer (EP 0 730 494) in view of Shimizu et al. (U.S. Patent No. 5,824,339) and Macek et al. (U.S. Patent No. 3,499,960) under 35 U.S.C. § 103(a).

CONCLUSION

Applicant submits that the present application is now in condition for allowance and requests early allowance of the pending claims.

The Commissioner is hereby authorized to charge any under payment or credit any over payment to Deposit Account No. 19-1345.

Respectfully submitted,

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